doi: 10.1111/j.1600-6143.2011.03606.x

Transplanting Kidneys Without Points for HLA-B Matching: Consequences of the Policy Change

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In 2003, the US kidney allocation system was changed to eliminate priority for HLA-B similarity. We report outcomes from before and after this change using data from the Scientific Registry of Transplant Recipients (SRTR). Analyses were based on 108 701 solitary deceased donor kidney recipients during the 6 years before and after the policy change, Racial/ethnic distributions of recipients in the two periods were compared (chi-square); graft failures were analyzed using Cox models. In the 6 years before and after the policy change, the overall number of deceased donor transplants rose 23%, with a larger increase for minorities (40%) and a smaller increase for non-Hispanic whites (whites) (8%). The increase in the proportion of transplants for non-whites versus whites was highly significant (p < 0.0001). Two-year graft survival improved for all racial/ethnic groups after implementation of this new policy. Findings confirmed prior SRTR predictions. Following elimination of allocation priority for HLA-B similarity, the deficit in transplantation rates among minorities compared with that for whites was reduced but not eliminated; furthermore, there was no adverse effect on graft survival.

Key words: Access to transplantation, allocation, HLA matching, kidney graft survival, kidney transplantation, minorities, policy, racial and ethnic disparities

Abbreviations: CI, confidence interval; ECD, expanded criteria donor; ESRD, end-stage renal disease; HLA, human leukocyte antigen; HRSA, Health Resources and

Services Administration; OPTN, Organ Procurement and Transplantation Network; PRA, panel reactive antibody; SCD, standard criteria donor; SRTR, Scientific Registry of Transplant Recipients; WL, waiting list.

Received 17 January 2011, revised 01 April 2011 and accepted for publication 18 April 2011

Introduction

Several studies have documented that access to deceaseddonor renal transplantation in the United States is proportionally greater for non-Hispanic whites (whites) than for African Americans (1–10). Such disparity exists both for placement on the waiting list and for receiving a kidney transplant after wait-listing (7). Early kidney transplantation experience established human leukocyte antigen (HLA) match as a powerful factor in posttransplant graft survival. However, dependence on HLA match grade to optimize graft survival decreased with the introduction of the calcineurin inhibitors cyclosporine and tacrolimus. The allocation priority assigned for HLA similarity was gradually reduced. Allocation priority for HLA-A similarity was eliminated in 1995. Following that change in allocation policy, US allocation rules directed deceased donor kidneys first to wait-listed candidates with no HLA A, B or DR mismatches with the donor and then according to a point system that assigned points for HLA-B and DR similarity, waiting time, pediatric age group, panel reactive antibody (PRA) level and previous living kidney donation (11). Each point was equivalent to a year spent on the waiting

The effect of HLA matching on graft survival is well established (12, 13). However, among recipients with some HLA mismatch at the A, B, or DR loci, the relative risk of graft failure is only weakly related to the number of mismatches at the HLA-A or HLA-B loci but increases with the number of mismatches at HLA-DR (14). Additional analyses by the Scientific Registry of Transplant Recipients (SRTR) predicted that the observed differences in transplantation rates by race/ethnicity would be reduced if points for HLA-B similarity were eliminated (14).

Those analyses were the basis for a change in national kidney allocation policy that was implemented on May 7, 2003. Before the policy change, points were assigned for

combined phenotypic similarity at the HLA-B and HLA-DR loci. Totals of zero, one and two mismatches for the combined HLA-B and HLA-DR loci were advantaged by points equivalent to 7, 5 and 2 years of waiting time, respectively. By comparison, the new kidney transplant allocation algorithm provides one or two points for one HLA-DR mismatch or zero HLA-DR mismatch, respectively, and no longer assigns any points for HLA-B similarity. We evaluated the effect of this change during the first 6 years following implementation of the new allocation policy compared with the 6 years before it. Comparisons were by race/ethnicity, examining access to deceased donor transplantation among wait-listed candidates and trends in graft survival.

Methods

Sources of data

We examined SRTR data for wait-listed deceased donor kidney transplant candidates, recipients and donors in the United States. The SRTR supplements data submitted to the Organ Procurement and Transplantation Network (OPTN) with vital status and graft failure information from the Social Security Death Master File and the Centers for Medicare & Medicaid End-Stage Renal Disease (ESRD) database.

Race and ethnicity were those noted on the waiting list or transplant recipient registration forms. Following the OPTN data collection format, Hispanic and non-Hispanic blacks were counted as African American. Hispanic and non-Hispanic Asians were counted as Asians. Hispanic and non-Hispanic Native Americans were counted as Native Americans. Non-Hispanic whites (whites) and Hispanic whites (Hispanic/Latinos) were tabulated and evaluated separately. Results for patients of other racial/ethnic groups are not reported because of small numbers.

Analytic methods: outcomes before and after policy change

Analyses were based on 108 701 patients who received a solitary deceased donor kidney transplant between May 7, 1997 and May 6, 2009. Racial/ethnic distribution and HLA distribution of deceased donor kidney transplant recipients were assessed during the 6 years before the allocation policy change and the 6 years following it. Significance was tested using chi-square statistics. The distribution of patients on the kidney waiting list or added to the kidney waiting list between May 7, 1997 and May 6, 2009 was computed.

Graft failure was analyzed 2 years after transplantation for those receiving a deceased donor kidney before versus after the policy change using a Cox model adjusted for donor sex, race, history of diabetes, cold ischemia time and expanded criteria donor (ECD) status, and for recipient age, sex, PRA, previous transplants, years of ESRD, previous transfusions and cause of ESRD. Graft failure was defined as the earliest date among death, retransplant of the same organ type, or initiation of maintenance dialysis. Preversus postimplementation graft failure percentage changes were analyzed overall and by racial/ethnic groups and HLA-B mismatch.

Human subjects statement

The Health Resources and Services Administration (HRSA), US Department of Health and Human Services, has determined that this study satisfies the criteria for the IRB exemption described in the 'Public Benefit and Service Program' provisions of 45 CFR 46.101(b) (5) and HRSA Circular 03. This study was approved by the HRSA SRTR project officer.

Results

The number and percentage of candidates on the kidney waiting list on May 6, 1997 and added to the waiting list in four 3-year intervals (May 7, 1997-May 6, 2000; May 7, 2000-May 6, 2003; May 7, 2003-May 6, 2006; and May 7, 2006–May 6, 2009) are shown by ethnicity group in Table 1. More than half of the candidates on the kidney waiting list on May 6, 1997 were non-white (53.5%). The percentage of African American patients on the list on this date was 35% and the percentage of new African American patients added to the list in each 3-year interval was considerably lower and remained relatively stable (28-29%). Similarly, Table 2 shows the distribution of patients who received a solitary deceased donor kidney transplant by race/ethnicity in the same four 3-year intervals from 1997 to 2009. The effect of the policy change that eliminated allocation priority for HLA-B similarity was evaluated among the 108 701 patients who received a solitary deceased donor kidney transplant between May 7, 1997 and May 6, 2009. There were 48 776 deceased donor transplants performed in the 6 years before the policy change and 59 925 transplants performed in the 6 years after policy implementation (a 23% increase overall). When comparing the 6 years before the policy change with the 6 years after, the number of transplants performed increased for each of the examined ethnic/racial groupings. However, each minority group exhibited a greater increase in the number of transplants than the average of 23%, whereas, whites exhibited a significantly smaller increase (8%; p < 0.0001). The percentage of whites receiving a deceased donor transplant declined after the policy change (54% to 47%) and most recently mirrors the percentage of whites newly added to waiting list (47%).

Prior to the policy change, the number of non-white transplants had been increasing and the number of white transplants declining (Table 2). To exclude the possibility that the change in transplant rates observed after the policy change might reflect only an early bolus effect rather than a longer-term consequence, we analyzed the numbers of white versus non-white transplant recipients by 6-month intervals over the 12 years of the study period (Figure 1). In the 6 years before the policy change, whites had more transplants than non-whites in all 12 of the 6-month intervals. This predominance reversed immediately after the policy change, such that in the 6 years following the new rule, non-whites received more transplants than whites in every 6-month interval (12 of 12). Overall, the increase in the proportion of transplants for nonwhites from pre- to postpolicy change was highly significant (p < 0.0001).

The percentage of zero mismatch kidney transplants decreased from almost 15% before the policy change to 13–14% after it (Table 2). Among mismatched recipients, however, there were substantial changes following the policy revision. As shown in the first two bars in Figure 2,

Table 1: Candidates on the kidney waiting list before and after policy change eliminating points for HLA-B similarity, 1997–2009

	On WL on May 6, 1997	May 6, 7	Added to WL May 7, 1997–May 6, 2000	WL May May 6, 10	Added to WL May 7, 2000–May 6, 2003	WL May ·May 6, ı3	Added to WL May 7, 2003–May 6, 2006	WL May May 6, 16	Added to WL May 7, 2006–May 6, 2009	lded to WL May 7, 2006–May 6, 2009	On WL on May 6, 2009	May 6, 19
Race/Ethnicity Group	z	%	z	%	z	%	z	%	z	%	z	%
Non-White	18 743	53.5	28 619	46.6	34 498	50.2	42 883	51.7	51 946	52.8	50 523	61.4
African American 13	2 375	35.3	17 327	28.2	19 864	28.9	23 389	28.2	28 625	29.1	28 627	34.8
	3 921	11.2	7 338	12.0	669 6	14.1	12 929	15.6	15 788	16.1	14 569	17.7
	2 005	5.7	3 294	5.4	4 116	6.0	5 383	6.5	6 303	6.4	6 146	7.5
Native American	441	1.3	650	1.1	703	1.0	870	1.1	932	1.0	851	1.0
Multiracial/Other	~	0.0	10	0.0	116	0.2	312	0.4	298	0.3	230	0.3
White	16 272	46.5	32 802	53.4	34 224	49.8	40 118	48.3	46 394	47.2	31 756	38.6
All 3	35 015	100	61 421	100	68 722	100	83 001	100	98 340	100	82 179	100

during the two 3-year periods before the policy change, 44–52% of the HLA mismatched transplant recipients received no points for combined HLA B-DR match, while about 17–21% received 5 points and 2% 7 points for HLA B-DR similarity. After the policy change, only about 38–40% of the mismatched transplant recipients received no points for HLA DR match, while about 49–50% received 1 point for HLA DR match and approximately 11–12% received 2 points for HLA DR match. As expected, matching for HLA-B declined when points for HLA-B match were removed: the percentage of two HLA-B mismatched transplant recipients increased from 46% (May 1997 to May 2000) to 72% (May 2006 to May 2009). In contrast, the percentage of two HLA-DR mismatches increased in those same intervals from 26% to 40%.

Overall, the adjusted relative graft survival percentages in the cohorts assessed 2 years after transplantation were higher after the policy change than before it (p < 0.05) (Table 3). From the 1997-2000 cohort to the 2006-2009 cohort, 2-year graft survival increased from 84.1% to 87.4% for white recipients and from 80.2% to 84.7% for African Americans recipients. Graft survival for Hispanic/Latinos, Asians and Native Americans was not statistically different among the four cohorts (May 1997 to May 2000, May 2000 to May 2003, May 2003 to May 2006 and May 2006 to May 2009), although it was higher among postpolicy transplant recipients than prepolicy recipients. Two-year graft survival increased, from 87.6% to 90.2% for zero mismatch recipients and from 83.0% to 86.7% for nonzero mismatch recipients from the 1997-2000 cohort to the 2006-2009 cohort. Substantial improvements were observed in the outcomes of both HLA-B mismatched and HLA-B nonmismatched transplants.

A subgroup analysis done separately for standard criteria donor (SCD) and ECD transplants showed that the trends in the percentage distribution by race/ethnicity displayed in Figure 1 were very similar for SCD kidney transplants; however, for ECD transplants, the percentage of organs received by nonwhites changed little during the last three time periods.

For illustration purposes, Figure 3 presents the active waiting list ($N=54\ 265$) on the day before the policy change (May 6, 2003), by time since wait-listing.

Discussion

The consequences of reducing allocation points for HLA similarity from two, five and seven to only one and two can be predicted from an understanding of the point-prevalent snapshot of time on the waiting list by years. Figure 3 illustrates that receiving seven or five points for zero or for one combined HLA-B and DR mismatch would allow candidates to jump ahead of almost the entire national waiting list. With similar waiting times, candidates given five and

Table 2: Deceased donor kidney transplants before and after policy change eliminating points for HLA-B similarity by race/ethnicity and zero mismatch, 1997–2009

	Deceas		nsplants Before ange	Deceased Donor Transplants After Policy Change				
	May 7, May 6		May 7, May 6		May 7, May 6		May 7, May 6,	
Race/Ethnicity	N	%	N	%	N	%	N	%
Non-White	10 592	44.2	11 936	48.1	14 677	52.0	16 952	53.5
African American	6 581	27.5	7 329	29.5	8 543	30.2	9 910	31.3
Hispanic/Latino	2 574	10.8	3 101	12.5	3 962	14.0	4 738	15.0
Asian	1 194	5.0	1 244	5.0	1 760	6.2	1 887	6.0
Native American	240	1.0	250	1.0	330	1.2	327	1.0
Multiracial/Other	3	0.0	12	0.0	82	0.3	90	0.3
White	13 351	55.8	12 897	51.9	13 569	48.0	14 727	46.5
Zero MM	3 760	14.7	3 660	14.7	4 056	14.4	4 107	13.0
All	23 943	100	24 833	100	28 246	100	31 679	100

seven points would receive organs before high-PRA candidates (who received a four-point advantage) (11). Therefore, reducing the allocation priority for HLA-DR similarity to a maximum of two points resulted in greater access to transplantation for children and high-PRA candidates.

The smaller percentage of zero HLA-DR mismatches is likely a reflection of the decrease in the number of points potentially provided for HLA-DR similarity. This resulted in a relative shift in overall allocation priority away from HLA-DR matching and toward waiting time.

The observed shift in organs from the white candidate pool to the minority pool persists even after the first 2 years of the new policy; it is consistent with and validates the results of the preimplementation SRTR statistical models (14). Under the previous allocation system,

candidates with disadvantaged antigens had accumulated years on the waiting list. Therefore a bolus effect after the policy change might have been expected to give minority candidates a transient waiting time advantage: it is possible the rapidity of change in allocation that was observed within the first 6 months of the new policy reflects such a bolus. However, analysis of each of the twelve 6-month periods following the policy change indicates that the number of deceased donor kidney transplants received by minority groups remained higher than that observed for white recipients. This suggests an apparent steadystate beyond that observed during the first 3 years following policy change. It is notable that while non-white candidates in aggregate are still not transplanted at rates proportionate to their representation on the waiting list. this deficit is reduced compared with that seen at the beginning of the study period. Furthermore, transplant

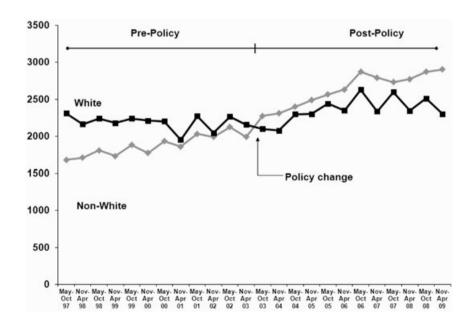
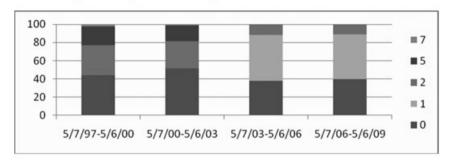


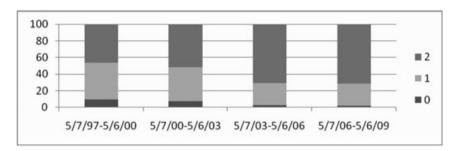
Figure 1: Number of transplants by race and 6-month period, May 7, 1997–May 6, 2009. The pre-policy period was from May 7, 1997 to May 6, 2003. The postpolicy period was from May 7, 2003 to May 6, 2009.

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Percent of patients by HLA B-DR points**



Percent of patients by HLA B MM



Percent of patients by HLA DR MM

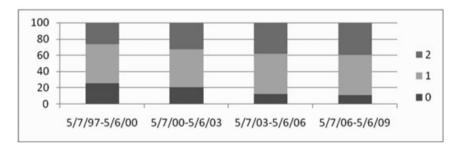


Figure 2: Distribution of nonzero mismatch kidney transplants by HLA B-DR points and by HLA B and HLA DR mismatch before and after the policy change*, 1997–2009. *Pre-Policy: 5/7/97-5/6/00 (N = 20,028) & 5/7/03-5/6/06 (N = 21,049); Post-Policy: 5/7/00-5/6/03 (N=23,948) & 5/7/06-5/6/09 (N = 27,318). **Each point provides allocation policy equal to one year of waiting time credit

percentages for each individual race/ethnic group closely approximate the frequency at which they are added to the waiting list.

The finding of lower graft failure rates in all racial/ethnic groups during the first 2 years after the policy change supports predictions from prior SRTR statistical models. These models indicated that no substantial graft survival effect by the level of HLA-B matching would be seen among recipients of mismatched deceased donor kidney transplants (14). There was a gradual improvement in deceased donor kidney graft survival over the recent decade (15). Therefore, the observed overall reduction in graft failure during the second 2-year period may be explained, in part, by this time trend. Although the general improvement in graft survival might have offset any potentially adverse effect of the policy change on graft outcomes, no decline in 2-year graft survival was observed following the implementation of this policy.

There is no evidence that the overall increase in minority transplantation has significantly affected graft survival, as the overall graft survival in the two eras after the policy change was 85.0% and 87.2%, respectively. These values are very close to the 85.1% and 87.2% observed, respectively, in the same time intervals in the white population. This suggests that the system-wide effect on 2-year allograft survival is minimal. This policy change, however, does not address the challenge of finding more organs to transplant. Other effects of this policy change, such as economic and quality of life benefit, have been suggested (16) but are beyond the scope of this study.

Given the prior large difference in transplantation rates after wait-listing observed for African Americans or Native Americans compared with whites (1–10), these new findings indicate a substantial reduction in the large advantage that wait-listed whites had with the prior policy. The racial composition of the additions to the waiting list

Table 3: Two-year adjusted graft survival before and after policy change eliminating points for HLA-B similarity by race and by HLA mismatch, 1997–2009

	2-Year Graft Survival ¹ (95% CI)							
	Pre-Policy	Transplants	Post-Policy Transplants					
Group	May 7, 1997–May 6, 2000	May 7, 2000-May 6, 2003	May 7, 2003–May 6, 2006	May 7, 2006–May 6, 2009				
White	84.1 (83.5, 84.7)	84.3 (83.7, 84.9)	85.1 (84.6, 85.7)	87.4 (86.8, 88.0)				
Non-White ²	83.1 (82.4, 83.8)	83.4 (82.8, 84.0)	84.7 (84.2, 85.3)	86.9 (86.4, 87.5)				
African American	80.2 (79.3, 81.2)	80.6 (79.7, 81.5)	82.3 (81.5, 83.1)	84.7 (84.0, 85.5)				
Hispanic/Latino	88.2 (86.9, 89.4)	87.9 (86.7, 89.0)	87.6 (86.6, 88.6)	89.7 (88.8, 90.7)				
Asian	87.0 (85.1, 88.9)	87.4 (85.6, 89.2)	88.4 (87.0, 89.9)	90.4 (89.0, 92.4)				
Native American	82.7 (78.3, 87.3)	83.8 (79.6, 88.2)	90.2 (87.2, 93.3)	87.1 (83.0, 91.3)				
Zero MM	87.6 (86.5, 88.7)	87.8 (86.7, 88.8)	88.8 (87.9, 89.8)	90.2 (89.2, 91.2)				
Non-Zero MM ²	83.0 (82.5, 83.5)	83.2 (82.8, 83.7)	84.3 (83.9, 84.8)	86.7 (86.3, 87.1)				
0 B MM	86.2 (84.8, 87.7)	84.8 (83.2, 86.5)	86.9 (84.3, 89.7)	88.6 (85.9, 91.5)				
1 B MM	83.6 (82.9, 84.4)	84.8 (84.1, 85.6)	84.5 (83.6, 85.3)	86.7 (85.9, 87.6)				
2 BMM	81.8 (81.0, 82.6)	81.9 (81.2, 82.6)	84.3 (83.8, 84.8)	86.7 (86.2, 87.2)				
All	83.6 (83.2, 84.1)	83.9 (83.4, 84.3)	85.0 (84.5, 85.4)	87.2 (86.8, 87.6)				

¹Adjusted 2-year graft survival following transplantation of a deceased-donor solitary kidney. Adjusted for donor sex, race, history of diabetes, cold ischemia time, ECD and recipient age, sex, PRA, previous transplants, years of ESRD, previous transfusions and cause of ESRD.

Notes: CI, 95% confidence interval. The N is shown in Table 2 by race and zero mismatch and in Figure 3 by non-zero mismatch.

3000 **Points for Prior B-DR Policy** 2500 **Number of Candidates** 2 5 2000 1500 1000 Points for **Current DR Policy** 500 0 1 2 6 7 Years on the Waitlist

Figure 3: Number of candidates on the kidney waiting list by years on the waiting list based on a cross-section of all wait-listed patients on May 6, 2003. Arrows indicate allocation policy of awarding points for HLA match (each point is equivalent to 1 year of waiting time).

has gradually increased for Hispanic/Latino and Asian candidates over the course of the 12-year time period (Table 1). This suggests that barriers to getting wait-listed have also improved, but, likely, only partially.

In summary, the current policy, which offers no allocation priority for HLA-B similarity and gives only one and two points for matches at HLA-DR, has improved access to transplantation for all minority groups and has not been associated with a decrease in 2-year graft survival during the first 6 years following the policy change. This new policy improved equity in access to deceased donor transplantation among wait-listed candidates without impairing posttransplant outcomes.

Acknowledgments

This research was funded through the Scientific Registry of Transplant Recipients, contract number 234–2005-37009C, from the Health Resources and Services Administration, US Department of Health and Human Services. The views expressed herein are those of the authors and not necessarily those of the US Government.

Findings were presented in part at the American Transplant Congress, Boston, MA, May 13–19, 2004 (Port FK, Ashby VB, Leichtman AB, McBride MA, Wynn JJ, Williams WW, Roberts JP, Rush SH and Wolfe RA. Eliminating points for HLA-B similarity increased kidney allocation to minority, pediatric, sensitized and zero MM candidates. Am J Transplant 2004;4 (Supp 8): 414) and at the Diversity and Disparity in Organ Transplantation Conference, Washington, D.C., September 21–22, 2005.

²Multiracial/Other race and unknown B mismatch not shown due to small sample size.

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This manuscript was edited by Caroline Shevrin of Arbor Research Collaborative for Health, Ann Arbor, MI.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

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